

REMARKS/ARGUMENTS

In response to the Final Office Action mailed June 22, 2007, Applicants propose to amend their application and request reconsideration in view of the proposed amendments and the following remarks. In this amendment, Claim 1 is proposed to be amended, no claims have been proposed to be added, claim 7 has been proposed to be cancelled without prejudice, and claims 9 and 10 have been previously withdrawn so that Claims 1, 3, 4, 5, and 9-10 are currently pending. No new matter has been introduced.

Claim 8, was rejected as being unpatentable over U.S. Patent No. 5,516,770 to Waranis et al. in view of EP0041795A2 to Sehgal and further in view of U.S. Patent No. 7,060,709 to Cooperstone et al. This rejection is respectfully traversed.

The MPEP, in section 706.02(j), sets forth the basic criteria that must be met in order to establish a *prima facie* case of obviousness:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. In *re* Vaeck, 947 F.2d, 488, 20 USPQ2d 1438 (Fed.Cir. 1991). See MPEP § 2143 - § 2143.03 for decisions pertinent to each of these criteria.

Section 2143.03 of the MPEP clarifies certain criteria in section 706.02(j).

"To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. In *re* Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." In *re* Wilson, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under

35 U.S.C. 103, then any claim depending therefrom is nonobvious.
In *re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).”

None of the references, whether taken alone or in combination disclose or suggest the invention of independent claim 1. Specifically, none of the references disclose or suggest a liquid formulation of rapamycin wherein the final solution comprises from about 4 mg/ml to about 15 mg/ml and is a true solution comprising rapamycin, ethanol, vitamin E TPGS and water. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Applicant would be grateful for the opportunity to conduct a telephonic or in-person interview of the Examiner believes it would be helpful in disposing of the present case.

A favorable action on the merits is earnestly solicited.

Respectfully submitted,

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